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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,575	11/14/2003	Stelios Tzannis	0180.00	1780

21968 7590 10/05/2007

NEKTAR THERAPEUTICS
201 INDUSTRIAL ROAD
SAN CARLOS, CA 94070

EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
10/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/714,575	TZANNIS ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/30/07*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-74* is/are pending in the application.

4a) Of the above claim(s) *1-30 and 60-74* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/30/07 has been entered.

2. Claims 1-74 are pending.
Claims 1-30 and 60-74 stand withdrawn from further consideration by the examiner, 37 C.F.R.§ 1.142(b) as being drawn to a nonelected invention.

Claims 31-59 are under consideration in the instant application.

3. The following rejection remains upon Applicants' amendments to the claims.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 31-59 stand rejected under 35 U.S.C. 102 (b) as being anticipated by U.S.Pat. No. 6,267,958 (IDS reference AK, of record).

The '958 patent teaches a stable reconstituted formulation comprising an antibody of about 100 mg/ml, diluent, buffer, sucrose as excipient (claims 1-8, 47 col. 17, lines 1-40, Table 5-6, in particular).

The '958 patent further teaches the antibody being full length, fragments (Fab, F(ab)2), murine, chimeric, CDR grafted as well as humanized (col. 7-8, 10-12), IgE or IgG (e.g. anti-HER2, Examples 1-2), conjugated (e.g. heteroconjugates, col. 14, lines 18-27) and the excipient being buffer including phosphate, histidine (col. 14-15 overlapping paragraph), diluent being sterile water (col. 9, lines 39-45, col. 17, lines 1-40) and surfactants (e.g. polysorbate, col. 15, lines 35-60). In addition, the '958 patent further teaches packaging of the composition in vial and syringes (col. 18, lines 24-49).

Claim 59 is included in this rejection as the '958 patent teaches the referenced antibody formulation being 99+% intact (Tables 4-6). The claimed invention is drawn to a reconstituted antibody formulation comprising an antibody formed from a spray-dried powder and an excipient and the patentability of the product does not depend on its method of production. Moreover, being "visually clear reconstituted composition within about 10min" is inherent property of the antibody composition comprising antibody, histidine and polysorbate. Thus, prior art teachings anticipate the claimed invention.

Applicants' arguments filed 5/30/07 have been fully considered but they are not persuasive.

Applicants traversed the rejection based on that the referenced composition will not inherently become visually clear reconstituted composition within about 10min as claimed.

As indicated in the previous office actions mailed 4/3/06 and 9/25/06, the claimed invention is drawn to a reconstituted antibody formulation comprising an antibody formed from a spray-dried powder and an excipient. The patentability of the product does not depend on its method of production. The claimed antibody formulation and the referenced antibody formulation both comprise an antibody, diluent, buffer and sucrose as an excipient (claims 1-8, 47 col. 17, lines 1-40, in particular). Examiner wishes to point out that the referenced composition and the claimed antibody composition are structurally identical and the characteristics "being visually clear upon reconstitution within about 10min" is inherent property of the claimed and the referenced antibody formulations.

Applicants further argue that the referenced formulation will not inherently become a visually clear composition within about 10min. The arguments of Applicant's counsel cannot take the place of evidence in the record. MPEP 2145. Thus, prior art teachings anticipate the claimed invention.

6. The following new rejection is necessitated by Applicants' amendment to the claims.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 31-59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

The specification as file does not provide a written description for the phrase " about 25mg/ml to **about 200mg/ml**". The specification on p. 22 lines 1-2 discloses the concentration ranges of "about 25mg/ml to **about 250mg/ml**". The particular concentration range has not been disclosed in the specification.

9. No claims are allowable.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on M-F,9-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim
Patent Examiner
Technology Center 1600
September 21, 2007

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